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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
COOK, LISA V	
ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/929,293	Applicant(s) DENNY ET AL.	
	Examin r Lisa V. Cook	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cov r sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-71* is/are pending in the application.

4a) Of the above claim(s) *2,4,5,8,9,24-29 and 32-71* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,6,7,10-23,30 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-71* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's species election of claim 3 for group A, claim 6 for group B, claim 7 for group C, and species V (claims 23, 30, and 31) for group D with traverse in Paper No. 10 is acknowledged. Applicant does not traverse the Restriction Requirement because it lacks patentable distinctness. But objects on the ground(s) "that a serious burden would not be required to examine all of the claims". This argument has been fully considered, but is not found convincing. Because Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

The Restriction Requirement is still deemed proper and is therefore made **FINAL.**

2. Claims 2, 4, 5, 8, 9, 24-29, and 32-71 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non elected invention (of record in paper #3), there being no allowable generic or linking claim. Currently, claims 1, 3, 6, 7, 10-23, 30 and 31 are under consideration.

Drawings

3. The Formal drawings submitted 8/14/01 in the instant application have been stamped approved by the Draftsperson under 37 CFR 1.84 or 1.152.

Priority

4. This application does not claim the benefit of a prior filed application.

Information Disclosure Statement

5. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 or applicant on PTO-1449 has cited the references they have not been considered.

6. The information disclosure statements filed 4/12/02-Paper #5, has been considered as to the merits prior to first action.

Specification

7. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 3, 6, 7, 10-23, 30 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. The term "predicting" is a relative term, which renders the claim 1 indefinite. The term "predicting" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. It is not clear if the claims are directed to method of determining a disease before it actually occurs. It is suggested that the term be eliminated from the claims in order to obviate this rejection.

B. Claims 11-13 are vague and indefinite in the assessment procedure because it is not clear as to what the method will encompass. As recited the metes and bounds of the method cannot be determined. For example it is not clear as to what will be considered high risk, medium risk, and low risk. If applicant intends to evaluate or relate mucin concentrations to particular measures of assessment (high, medium, and low), the values should be included to clearly indicate Applicant's intended meaning. (i.e. mucin levels of 0-200 units/ml are indicative of high disease risk). Appropriate correction is required.

C. Claim 31 is indefinite and ambiguous in the recitation of the abbreviations DFT, DMT, and DMFS, because abbreviations can indicate a number of entities. Applicant should amend the claims to recite the proper identification of the dental caries.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I. Claims 1, 7, and 14-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Nielsen et al. (Journal of Dental Research, Vol.75, No.11, pages 1820-1826, 1996).

Nielsen et al. teach the detection of a component of MUC7 (MG2) in salivary samples. Specifically monoclonal antibodies Mab PANH3 against a synthetic peptide derived from MUC7 (MG2) were used to stain concentrated saliva samples in western blot analysis and frozen sections of human salivary glands. The antibody probes were taught to be useful in studying mucin expression in diseases of the salivary gland. See abstract. Isolation of the mucin was conducted in a SDS-Page and Western blot system. See page 1822 1st column.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 3, 6 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (Journal of Dental Research, Vol.75, No.11, pages 1820-1826, 1996) in view of Belce et al. (Tohoku Journal of Experimental Medicine, 11/2000, Vol.192, No.3, pages 219-225, Abstract Only).

Please see Nielsen et al. as set forth above.

Nielsen et al. differ from the instant invention in not specifically teaching the measurement of sialic acid in unstimulated saliva.

However, Belce et al. disclose the measurement of the component sialic acid in unstimulated saliva specimens. The researchers found the decreased levels of salivary sialic acid may be a possible factor leading to oral complications of diabetes mellitus (disease). See abstract.

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the measurement of sialic acid in unstimulated saliva samples as taught by Belce et al. in the salivary based mucin assessment method for disease of Nielsen et al. because Belce et al. taught that sialic acid levels in unstimulated saliva was important is evaluating oral complications/disease such as diabetes mellitus.

Therefore, one of ordinary skill at the time of the invention would have been motivated to detect sialic acid levels in unstimulated saliva in order to determine diabetes mellitus in a subject/sample.

II. Claims 11-13, 20-22 and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (Journal of Dental Research, Vol.75, No.11, pages 1820-1826, 1996) in view of Belce et al. (Tohoku Journal of Experimental Medicine, 11/2000, Vol.192, No.3, pages 219-225, Abstract Only) and in further view of Astor et al. (Ear, Nose & Throat Journal, 7/1999, 78(7), pages 476-479.

Nielsen et al. in view of Belce et al. are set forth above.

Nielsen et al. in view of Belce et al. differ from the instant invention in not teaching methods evaluating male and female patients between the ages of 18 and 35 for dental caries risk assessment.

However, Astor et al. teach methods of assessing patients at risk for dental caries. In particular Xerostomia or dry mouth was evaluated in male and female patients. Saliva content and compositions were assed for this disease. It was determined that "natural aging brings about significant changes in the composition and mixture of saliva, primarily a decrease ptyalin and an increase in mucin". Page 477 1st column 3rd paragraph. Although Xerostomia or dry mouth is usually associated with the elderly, it can also occur with depression, mucositis, oral infections, dental infections, dysphagia, speech disorders, and digestive problems. Therein reading on subjects/patients between the age of 18 and 35. Page 476 2nd column.

Patients were at risk for developing Xerostomia or dry mouth as a systemic disease or when they were undergoing drug therapy or radiation therapy. Page 477 2nd column. The early detection of the dental caries disease Xerostomia or dry mouth is taught to be useful in treatments and the prevention of complications. Page 476 2nd column 2nd paragraph.

It would have been obvious to one of ordinary skill in the art at the time of the invention to evaluate dental caries diseases such as Xerostomia or dry mouth in the saliva (evaluating ptyalin and mucin) of patients at any age as a means to assess/treat/prevent the diseases as taught by Astor et al. in the saliva mucin method of Nielsen et al. in view of Belce et al. because Astor et al. taught that salivary physiology was significant in evaluating patients disorders. Further the function of saliva is diverse and critical and mucin secretion is apart of that criticality. See page 476 Salivary physiology.

Therefore, one of ordinary skill at the time of the invention would have been motivated to assess mucin levels in human saliva as a measure of disease/disorders like dental caries in order to detect potential problems and possibly prevent their spread.

III. Claims 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (Journal of Dental Research, Vol.75, No.11, pages 1820-1826, 1996) in view of Belce et al. (Tohoku Journal of Experimental Medicine, 11/2000, Vol.192, No.3, pages 219-225, Abstract Only) and in further view of Astor et al. (Ear, Nose & Throat Journal, 7/1999, 78(7), pages 476-479.

Nielsen et al. in view of Belce et al. and in further view of Astor et al. are set forth above.

Nielsen et al. in view of Belce et al. and in further view of Astor et al. differ from the instant invention in not specifically teaching the units per milliter as the measurement parameter.

However, changes in units of measurement is viewed as mere optimization of the teachings of Nielsen et al. in view of Belce et al. and in further view of Astor et al.

Nielsen et al. in view of Belce et al. and in further view of Astor et al. discloses the claimed invention except for teaching the units per milliter as the measurement parameter. It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize units per milliter as the measurement parameter, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

11. For reasons aforementioned, no claims are allowed.

Remarks

12. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

A. Goldstein et al. (U.S. Patent #5,736,322) disclose an oral fluid standard comprising a mucin and a protease inhibitor.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 308-4556, which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (703) 305-0808. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Lisa V. Cook
CM1-7B17
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8/24/03

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08/24/03